DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 20, 2014

Vascular Solutions, Inc.
Adam Ettl
Sr. Regulatory Product Specialist
6464 Sycamore Court North
Minneapolis, Minnesota 55369

Re: K143038
Trade/Device Name: Gel-block 10x Embolization Pledgets
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: October 21, 2014
Received: October 23, 2014

Dear Adam Ettl,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143038

Device Name
Gel-Block 10x embolization pledgets

Indications for Use *(Describe)*
The Gel-Block 10x embolization pledgets is intended for use in the embolization of hypervascular tumors and arteriovenous malformations (AVMs).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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2 510(k) Summary

[As required by 21 CFR 807.92]

Date Prepared: October 21, 2014

510(k) Number: K143038

Submitter's Name / Contact Person

Manufacturer
Vascular Solutions, Inc.
6464 Sycamore Court North
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person
Adam Ettl
Sr. Regulatory Product Specialist
Tel: 763-656-4300
Fax: 763-656-4253

General Information

Trade Name	Gel-Block 10x embolization pledgets
Common / Usual Name	Device, vascular, for promoting embolization
Classification Name	870.3300, KRD - vascular embolization device; Class II
Predicate Device	K113266 - Gel-Block embolization pledgets (Vascular Solutions, Inc.)

Device Description

The Gel-Block 10x embolization pledgets is an embolic device consisting of 10 radially compressed porcine derived gelatin pledgets packaged in one transparent glass vial. A delivery syringe is provided for introduction of the pledgets into the delivery catheter (not included). The pledgets are available in three sizes compatible with a delivery catheter having a minimum inner diameter of ≥ 0.038", ≥ 0.027", or ≥ 0.021". When unconstrained in a blood vessel, each pledget will occlude blood flow by swelling to a specified swell size. The finished product is sterilized by electron-beam irradiation and is intended for single use only.

Intended Use / Indications

The Gel-Block 10x embolization pledgets is intended for use in embolization of hypervascular tumors and arteriovenous malformations (AVMs).

Technological Characteristics

The porcine derived gelatin pledgets in the Gel-Block 10x embolization pledgets and the Gel-Block embolization pledgets are identical. The only differences between the subject and predicate device are the package materials and configuration. The subject device contains 10 pledgets in a glass vial with a screw cap, while the predicate device contains two delivery assemblies each containing one pledget. The subject device does not include or require the use of the delivery assemblies as the pledgets are removed from the glass vial and placed directly in the tip of the delivery syringe. The subject and predicate devices each contain one delivery syringe, either 1cc or 3cc depending on the model. The

subject device components (glass vial with screw cap, 10 pledgets, and one delivery syringe) are provided on a packing card and placed in a Tyvek pouch. The predicate device components (two individual pledgets packaged in separate delivery assemblies and one delivery syringe) are provided in a thermoformed tray with Tyvek lid that is placed in a Tyvek pouch. The subject and predicate devices are packaged in a retail box each containing five Tyvek pouches.

Substantial Equivalence and Summary of Studies

The technological differences between the subject and predicate devices have been evaluated through biocompatibility and bench tests to provide evidence of substantial equivalence. The Gel-Block 10x embolization pledgets is substantially equivalent to the specified predicate device based on comparisons of the device functionality, technological characteristics, and indications for use. Therefore the only new design verification test necessary was deliverability. Package validation tests and sterilization validation tests were completed to support the new package configuration. Biocompatibility tests were required to assess the Gel-Block 10x embolization pledgets package materials.

The following biocompatibility tests were performed as recommended by ISO 10993-1:

- Cytotoxicity
- Sensitization
- Irritation/Intracutaneous Reactivity
- Acute Systemic Toxicity
- Hematology

The results of the deliverability, package, sterilization and biocompatibility tests met the specified acceptance criteria and did not raise new safety or performance issues. Therefore, the Gel-Block 10x embolization pledgets is substantially equivalent to the predicate device.